

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: KENDREW, Steven Gary *et al.*

Confirmation No.: 5863

Serial No.: 10/580,781

Group Art Unit: 1623

Filing Date: June 13, 2007

Examiner: PESELEV, Elli

For: *Erythromycins and Process for Their Preparation*

MAIL STOP PATENT EXT.

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM UNDER
35 USC §154(b) and 37 CFR §1.705(d)

This is a request for reconsideration of patent term adjustment pursuant to 37 CFR §1.705(d), according to which the applicant may request reconsideration within two months from the date the patent issued if the patent indicates or should have indicated a revised patent term adjustment. Applicants respectfully seek **433 days** of patent term adjustment.

Accompanying this request is the required processing fee set forth in 37 CFR §1.18(e). The statement of facts supporting this request is set forth below pursuant to 37 CFR §1.705(b)(2). Note, the issues raised herein under 37 CFR §1.703(b) and §1.705(a) could not have been raised prior to payment of the issue fee because the total term eligible for extension could not have been calculated until actual issuance of the patent by the USPTO.

Statement of Relevant Facts/Dates:

There are several dates relevant to the calculation of patent term adjustment. Those dates are summarized below:

30-month date for Application: May 29, 2006
Date of Completion of 35 USC §371 Requirements: June 13, 2007
3-year Pendency ended: May 29, 2009
35 USC §154(b)(1)(B) "3-year" PTA began: May 30, 2009
Final Office Action mailing date: August 21, 2009
Notice of Appeal filed: January 21, 2010
Notice of Allowance mailing date: June 15, 2010
Issue date: October 5, 2010

Patent Term Adjustment Under 35 USC §154

35 USC §154(b)(1) governs patent term guarantees – patent term adjustments available to compensate for delays in prosecution due to USPTO delay. 35 USC §154(b)(1) has two main sections. 35 USC §154(b)(1)(A) governs situations that arise under the "14-4-4-4 Rule", where delay occurs for failure of the Office to issue a first action within 14 months from filing of the application, or within 4 months after various applicant responses. Delay under this subsection is referred to as "A delay." 35 USC §154(b)(1)(B) governs situations under which pendency of the application exceeds 3 years from filing due to USPTO delay. Delay under this subsection is referred to as "B delay."

Patent Term Adjustment due under "A delay" is 25 days

Under 35 USC §154(b)(1)(A), the applicant is guaranteed prompt USPTO responses. If the issue of an original patent is delayed due to failure of the Office to engage in reasonable efforts to conclude prosecution, the term of the patent shall be extended in accordance with 37 CFR §1.703(a).

In this application, the Office failed to issue the Notice of Allowance within 4 months of Applicant filing the Notice of Appeal. In fact, the Office did not issue an Office Action until 25 days after the 4-month time limit had passed. **25 days** was the total A delay on behalf of the Office.

Patent Term Adjustment due under "B delay" is 494 days

Under 35 USC §154(b)(1)(B), the applicant is guaranteed of no more than a 3-year application pendency. If the issuance of a patent is delayed beyond 3 years due to USPTO delay, then the term of the patent shall be extended in accordance with 37 CFR §1.703(b). The term of a patent shall be extended 1 day for each day of Office delay after the end of the 3-year period until the patent is issued, not including any delay in the processing of the application requested by the applicant.

According to 35 USC §154(b)(1)(b), B delay begins to accumulate 3 years after the application was actually filed. 37 CFR §1.702 interprets "actually filed" as the commencement of a 35 USC §371 national stage under either 35 USC §371(b) or (f). The 30-month date for this application was May 29, 2006.

Per 37 CFR §1.703(b), the B delay is calculated from the day after the three year period ended, *i.e.*, May 30, 2009, and ending on the date the patent issued, October 5, 2010, which is calculated to be 494 days.

Applicant Delay is 61 days

According to 35 USC §154(b)(2)(c), the period of adjustment shall be reduced for that period of time over 3 months that an applicant fails to respond to a notice of rejection. In this application, the applicant delayed 61 days after the three month deadline for response to the Final Office Action. Accordingly, the total applicant delay is 61 days.

Overlapping period and total patent term adjustment

According to §1.703(f), the term of a patent is entitled to adjustment under §1.702 and the term shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704.

The subject of overlap has been addressed in Wyeth v. Kappos, where the Court of Appeals for the Federal Circuit held that the only way periods of time can "overlap" is if the A and B delays occur on the same day, and that the B delay begins when the PTO has failed to issue a patent within three years, not before.¹

¹ Wyeth v. Dudas, 580 F. Supp. 2d 138, 142, affirmed by CAFC as Weyth v. Kappos (January 7, 2010).

Here, the entire A delay of 25 days attributable to the Office occurred during the B delay period. This **25-day** overlap period should be subtracted from the Patent Term Adjustment.

Calculation of Patent Term Adjustment

Applicants contend that the total patent term adjustment the above patent is entitled to, as explained herein, should be **433 days** (25 days of A delay + 494 days of B delay – 61 days of Applicant delay – 25 days of overlap).

CONCLUSION

Applicants submit that in view of the foregoing, the subject patent is entitled to a total of **433 days** of patent term adjustment. Applicants hereby respectfully request reconsideration of the patent term adjustment.

If a telephone conference would help the Office determine this matter, the Office is encouraged to call the undersigned attorney. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR §1.18, and any necessary extension of time fees, to Deposit Account No. 07-1392.

Respectfully submitted,

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